

GEORGIA MEDICAID FEE-FOR-SERVICE CYSTIC FIBROSIS, ORAL PA SUMMARY

Preferred	Non-Preferred
Kalydeco (ivacaftor) Orkambi (lumacaftor/ivacaftor) Symdeko (tezacaftor/ivacaftor and ivacaftor) Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor)	N/A

LENGTH OF AUTHORIZATION: 1 Year

NOTE: All preferred agents require prior authorization (PA).

PA CRITERIA:

Kalydeco

Approvable for members 4 months of age or older with a diagnosis of cystic fibrosis (CF) who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a CF mutation test: *G551D*, *G1244E*, *G1349D*, *G178R*, *G551S*, *S1251N*, *S1255P*, *S549N*, *S549R*, *R117H*, *A455E*, *A1067T*, *D110E*, *D110H*, *D579G*, *D1152H*, *D1270N*, *E56K*, *E193K*, *F1052V*, *F1074L*, *G1069R*, *K1060T*, *L206W*, *P67L*, *R74W*, *R117C*, *R347H*, *R352Q*, *R1070Q*, *R1070W*, *S945L*, *S977F*, *E831X*, *711+3A→G*, *2789+5G→A*, *3272-26A→G* or *3849+10kbC→T*.

Orkambi

❖ Approvable for members 2 years of age or older with a diagnosis of cystic fibrosis who are homozygous for the *F508del* mutation in the CFTR gene as detected by a CF mutation test.

<u>Symdeko</u>

Approvable for members 6 years of age and older with a diagnosis of cystic fibrosis who are homozygous for the *F508del* mutation in the CFTR gene as detected by a CF mutation test or who have one of the following mutations in the CFTR gene as detected by a CF mutation test: *A455E*, *A1067T*, *D110E*, *D110H*, *D579G*, *D1152H*, *D1270N*, *E56K*, *E193K*, *F1052V*, *F1074L*, *K1060T*, *L206W*, *P67L*, *R74W*, *R117C*, *R347H*, *R352Q*, *R1070W*, *S945L*, *S977F*, *E831X*, *711+3A→G*, *2789+5G→A*, *3272-26A→G* or *3849+10kbC→T*.

Trikafta

❖ Approvable for members 12 years of age or older with a diagnosis of cystic fibrosis who have at least one *F508del* mutation in the CFTR gene as detected by a CF mutation test.



EXCEPTIONS:

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827**.

PREFERRED DRUG LIST:

• For online access to the Preferred Drug List (PDL), please go to http://dch.georgia.gov/preferred-drug-lists.

PA and APPEAL PROCESS:

 For online access to the PA process, please go to http://dch.georgia.gov/prior-authorization-process-and-criteria and click on Prior Authorization (PA) Request Process Guide.

QUANTITY LEVEL LIMITATIONS:

For online access to the current Quantity Level Limits (QLL), please go to
 <u>www.mmis.georgia.gov/portal</u>, highlight Pharmacy and click on <u>Other Documents</u>, then
 select the most recent quarters QLL List.